What Is Claimed Is:

1. A method of treating cancer or metastasis thereof in a mammal, comprising:

administering into a muscle tissue of said mammal a non-infectious, non-integrating DNA encoding a cytokine, or an active fragment thereof, through operable association with one or more ~~transcription-control~~ elements, wherein said DNA is administered free from *ex vivo* cells;

such that the cytokine encoded by said DNA is expressed *in vivo*, and

such that said cytokine is present in the blood stream of said mammal in an amount effective to treat said cancer, or metastasis thereof.

2. The method of claim 1, wherein said one or more transcription control elements comprises a promoter.

3. The method of claim 2, wherein said one or more transcription control elements comprises a polyadenylation signal and a transcription termination signal.

4. The method of claim 2, wherein said cancer is selected from the group consisting of renal cell carcinoma, colorectal carcinoma, lymphoma, Kaposi's sarcoma, melanoma, prostate cancer, ovarian cancer, lung cancer, liver cancer, head and neck cancer, bladder cancer, uterine cancer, bone cancer, leukemia, breast cancer, non-melanoma skin cancer, glioma, solid cutaneous tumor, epidermoid carcinoma, metastases of any of thereof, and combinations of any of thereof.

5. The method of claim 4, wherein said cancer is a lung metastasis of any of said cancers.

6. The method of claim 4, wherein said cancer is a liver metastasis of any of said cancers.

7. The method of claim 2, wherein said muscle tissue is selected from the group consisting of skeletal muscle, smooth muscle, or myocardium.

8. The method of claim 2, wherein said DNA is administered intramuscularly.

9. The method of claim 2, wherein said cytokine is selected from the group consisting of IFNω, IFNα, IFNτ, IFNγ, IFNβ, IL-1, IL-2, IL-4, IL-7, IL-12, IL-15, IL-18, GM-CSF, and a combination of any of thereof.

10. The method of claim 2, wherein said active fragment of a cytokine is selected from the group consisting of an active fragment of IFNω, an active fragment of IFNα, an active fragment of IFNτ, an active fragment of IFNγ, an active fragment of IFNβ, an active fragment of IL-1, an active fragment of IL-2, an active fragment of IL-4, an active fragment of IL-7, an active fragment of IL-12, an active fragment of IL-15, an active fragment of IL-18, an active fragment of GM-CSF, and a combination of any of thereof.

11. The method of claim 9, wherein said cytokine is an interferon ω.

12. The method of claim 11, wherein said interferon ω is a polypeptide comprising amino acids 1 to 172 in SEQ ID NO:8.

13. The method of claim 12, wherein said interferon ω is a polypeptide comprising amino acids -23 to 172 in SEQ ID NO:8.

14. The method of claim 11, wherein said DNA is VR4151 (SEQ ID NO:4).

15. The method of claim 9, wherein said cytokine is an interferon α.

16. The method of claim 15, wherein said interferon α is a polypeptide comprising amino acids 1 to 166 of SEQ ID NO:10.

17. The method of claim 16, wherein said interferon α is a polypeptide comprising amino acids -23 to 166 of SEQ ID NO:10.

18. The method of claim 15, wherein said DNA is VR4112 (SEQ ID NO:2).

19. The method of claim 9, wherein said cytokine is an interleukin-2.

20. The method of claim 19, wherein interleukin-2 is a polypeptide comprising amino acids 58 to 105 of SEQ ID NO:14.

21. The method of claim 20, wherein interleukin-2 is a polypeptide comprising amino acids 20 to 126 of SEQ ID NO: 14.

22. The method of claim 19, wherein said DNA is VR1103 (SEQ ID NO:25).

23. The method of claim 2, wherein said DNA encodes interferon ω, and

wherein said DNA is administered intramuscularly.

24. The method of claim 23, wherein said cancer is melanoma or metastasis thereof.

25. The method of claim 24, wherein said cancer is metastasis of melanoma.

26. The method of claim 25, wherein the metastasis of melanoma is lung metastasis.

27. The method of claim 23, wherein said cancer is glioma.

28. The method of claim 23, wherein said cancer is epidermoid carcinoma.

29. The method of claim 2, wherein said DNA encodes interferon α, and

wherein said DNA is administered intramuscularly.

30. The method of claim 29, wherein said cancer is melanoma or metastasis thereof.

31. The method of claim 30, wherein said cancer is metastasis of melanoma.

32. The method of claim 31, wherein the metastasis of melanoma is lung metastasis.

33. The method of claim 29, wherein said cancer is glioma.

34. The method of claim 29, wherein said cancer is epidermoid carcinoma.

35. The method of claim 2, wherein said DNA is dissolved in an aqueous solution.

36. The method of claim 35, further comprising sodium phosphate dissolved in said aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM.

37. The method of claim 36, further comprising sodium phosphate dissolved in said aqueous solution at a molar concentration ranging from about 100 mM to about 150 mM.

38. The method of claim 2, wherein said DNA is administered free from association with transfection-facilitating proteins, viral particles, liposomes, cationic lipids, and calcium phosphate precipitating agents.

39. The method of claim 2, wherein said DNA is administered as a complex of said DNA and one or more cationic compounds selected from the group consisting of cationic lipids, cationic peptides, cationic proteins, cationic polymers other than lipids or peptides, and mixtures thereof.

40. The method of claim 39, wherein said one or more cationic compounds are one or more cationic lipids.

41. The method of claim 40, wherein said complex further comprises one or more neutral lipids.

42. The method of claim 2, wherein said DNA operably encodes one or more additional cytokines.

43. The method of claim 2, wherein said DNA comprises a region regulating gene expression.

44. The method of claim 43, wherein said region regulating gene expression is cell specific or tissue specific.

45. The method of claim 44, wherein said region is tumor cell or tumor tissue specific.

46. A method of treating cancer, or metastasis thereof, in a mammal, comprising:

the method of claim 2 in combination with one or more additional cancer treatment methods selected from the group consisting of surgery, radiation therapy, chemotherapy, immunotherapy, and gene therapy.

47. The method of claim 46, wherein said DNA is administered prior to the commencement of said one or more additional cancer treatment methods.

48. The method of claim 46, wherein said DNA is administered during the practice of said one or more additional cancer treatment methods.

49. The method of claim 46, wherein said DNA is administered after the end of said one or more additional cancer treatment methods.

50. The method of claim 2, wherein said mammal is human.

51. A method of treating cancer or metastasis thereof in a mammal, comprising:

administering into a muscle tissue of said mammal a non-infectious messenger RNA encoding a cytokine, or an active fragment thereof, wherein said messenger RNA is administered free from *ex vivo* cells;

such that the cytokine encoded by said messenger RNA is expressed *in vivo*, and

such that said cytokine is present in the blood stream of said mammal in an amount effective to treat said cancer, or metastasis thereof.

52. A pharmaceutical composition comprising about 1 ng to 20 mg of a non-infectious, non-integrating polynucleotide construct comprising a polynucleotide selected from the group consisting of:

(a) a polynucleotide that hybridizes under stringent conditions to the nucleotide sequence of SEQ ID No. 7 or the complement thereof,

wherein said polynucleotide sequence encodes a polypeptide that has antiproliferative activity when added to NIH-OVCAR3 cells *in vitro*;

(b) a polynucleotide that encodes a polypeptide comprising an amino acid sequence which, except for at least one but not more than 20 amino acid substitutions, deletions, or insertions, is identical to amino acids -23 to 172 or 1 to 172 in SEQ ID No. 8, wherein said polypeptide has antiproliferative activity when added to NIH-OVCAR3 cells *in vitro*; and

(c) a polynucleotide that encodes a polypeptide comprising amino acids 86 to 172 in SEQ ID No. 8, wherein said polypeptide has antiproliferative activity when added to NIH-OVCAR3 cells *in vitro*;

wherein said polynucleotide is dissolved in an aqueous solution; and

sodium phosphate dissolved in said aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM, and reaction, association, or dissociation products thereof.

53. The method of claim 52, wherein said sodium phosphate is dissolved in said aqueous solution at a molar concentration ranging from about 100 mM to about 150 mM.

54. A pharmaceutical composition obtained by complexing about 1 ng to 20 mg of a non-infectious, non-integrating polynucleotide construct comprising a polynucleotide selected from the group consisting of:

(a) a polynucleotide that hybridizes under stringent conditions to the nucleotide sequence of SEQ ID No. 7 or the complement thereof,

wherein said polynucleotide sequence encodes a polypeptide that has antiproliferative activity when added to NIH-OVCAR3 cells *in vitro*;

(b) a polynucleotide that encodes a polypeptide comprising an amino acid sequence which, except for at least one but not more than 20 amino acid substitutions, deletions, or insertions, is identical to amino acids -23 to 172 or 1 to 172 in SEQ ID No. 8, wherein said polypeptide has antiproliferative activity when added to NIH-OVCAR3 cells *in vitro*; and

(c) a polynucleotide that encodes a polypeptide comprising amino acids 86-172 of SEQ ID No. 8, and wherein said polypeptide has antiproliferative activity when added to NIH-OVCAR3 cells *in vitro;*

wherein said polynucleotide is dissolved in an aqueous solution; and

sodium phosphate dissolved in said aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM, and reaction, association, or dissociation products thereof.

55. The method of claim 54, wherein said sodium phosphate is dissolved in said aqueous solution at a molar concentration ranging from about 100 mM to about 150 mM.

56. The method of claim 54, wherein said polynucleotide is DNA operably linked to a promoter.

57. The method of claim 54, wherein said polynucleotide is RNA.

58. The method of claim 54, wherein said mammal is a human.

59. A method of treating cancer in a mammal, comprising:

administering into a tissue of said mammal a non-infectious, non-integrating polynucleotide in aqueous solution, wherein said polynucleotide encodes a cytokine, or an active fragment thereof, selected from the group consisting of an interferon ω, an interferon α, a combination of an interferon ω and an interferon α, and an active fragment of any of thereof; and

sodium phosphate dissolved in said aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM, and reaction, association, or dissociation products thereof;

such that said cytokine is delivered to a tumor in a therapeutically effective amount.

69. The method of claim 59, wherein said sodium phosphate is dissolved in said aqueous solution at a molar concentration ranging from about 100 mM to about 150 mM.

61. The method of claim 59, wherein said polynucleotide construct is administered free from *ex vivo* cells or *ex vivo* cellular material.

62. The method of claim 59, wherein said construct is administered directly into a tumor.

63. The method of claim 59, wherein said construct is free from association with transfection-facilitating proteins, viral particles, liposomes, cationic lipids, and calcium phosphate precipitating agents.

64. The method of claim 59, wherein said polynucleotide is DNA operably linked to a promoter.

65. The method of claim 59, wherein said polynucleotide is RNA.

66. A method of treating cancer in a mammal, comprising:

administering into a body cavity of said mammal a non-infectious, non-integrating polynucleotide construct comprising a polynucleotide encoding a cytokine, or an active fragment thereof, such that said cytokine is delivered to a tumor in a therapeutically effective amount.

67. The method of claim 66, wherein said cytokine is selected from the group consisting of an interferon ω, an interferon α, and an interleukin-2.

68. The method of claim 66, wherein said polynucleotide construct is administered free from *ex vivo* cells or *ex vivo* cellular material.

69. The method of 66, wherein said tumor disseminates in a body cavity.

70. The method of 69, wherein the body cavity is peritoneal cavity.

71. The method of claim 66, wherein said construct is free from association with transfection-facilitating proteins, viral particles, and calcium phosphate precipitating agents.

72. The method of claim 66, wherein said construct is administered as a complex of said construct and one or more cationic lipids.

73. The method of claim 72, wherein said complex further comprising one or more neutral lipids.

74. The method of claim 73, wherein said polynucleotide construct is complexed with (±)-N-(2-hydroxyethyl)-N,N-dimethyl-2,3-bis(tetradecyloxy)-1-propaniminium bromide and 1,2-dioleoyl-glycero-3-phosphoethanolamine.

75. The method of claim 66, wherein said polynucleotide is DNA operably linked to a promoter.

76. The method of claim 66, wherein said polynucleotide is RNA.

77. The method of claim 66, wherein said mammal is a human.

78. A method of selectively transfecting malignant cells in a body cavity of a mammal, comprising:

administering into a body cavity of said mammal a non-infectious, non-integrating polynucleotide construct comprising a polynucleotide encoding a molecule, or an active fragment thereof, such that said molecule is delivered substantially to and expressed in malignant cells within said body cavity.

79. The method of 78, wherein said molecule is a cytokine.

80. The method of claim 79, wherein said cytokine is selected from the group consisting of an interferon ω, an interferon α, and an interleukin-2.

81. The method of claim 78, wherein the body cavity is peritoneal cavity.

82. The method of claim 78, wherein said polynucleotide construct is administered free from *ex vivo* cells or *ex vivo* cellular material.

83. The method of claim 78, wherein said construct is free from association with transfection-facilitating proteins, viral particles, and calcium phosphate precipitating agents.

84. The method of claim 78, wherein said construct is administered as a complex of said construct and one or more cationic lipids.

85. The method of claim 84, wherein said complex further comprising one or more neutral lipids.

86. The method of claim 85, wherein said polynucleotide construct is complexed with (±)-N-(2-hydroxyethyl)-N,N-dimethyl-2,3-

bis(tetradecyloxy)-1-propaniminium bromide and 1,2-dioleoyl-glycero-3-phosphoethanolamine.

87. The method of claim 78, wherein said polynucleotide is DNA operably linked to a promoter.

88. The method of claim 78, wherein said polynucleotide is RNA.

89. The method of claim 90, wherein said mammal is a human.

90. A composition comprising:

(a) about 1 ng to about 30 mg of a polynucleotide in aqueous solution which operably encodes a polypeptide upon delivery to vertebrate cells *in vivo*;

(b) sodium phosphate dissolved in said aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM, and reaction, association, or dissociation products thereof.

91. The composition of claim 90, wherein said sodium phosphate is present at a molar concentration of about 100 mM to about 150 mM.

92. The composition of claim 90, wherein said sodium phosphate is present at a molar concentration of about 150 mM.

93. The composition of claim 90, which is substantially free of chloride ion.

94. The composition of claim 90, wherein said polynucleotide is DNA operably associated with a promoter.

95. The composition of claim 90, wherein said polynucleotide is RNA.

96. The composition of claim 90, wherein said polypeptide is selected from the group consisting of a therapeutic polypeptide, an antigenic polypeptide, an immunogenic polypeptide, an immunomodulatory polypeptide, and a functional self polypeptide.

97. The composition of claim 90, further comprising a transfection facilitating agent selected from the group consisting of calcium phosphate, alum, gold, tungsten, or other metal particles, peptides, proteins, and polymers.

98. A method for delivering a polypeptide to a vertebrate, comprising administering into a tissue or cavity of said vertebrate the composition of claim 90;

wherein said polypeptide is expressed in the vertebrate in an amount sufficient to be detectable.

99. A method for delivering a therapeutic polypeptide to a vertebrate, comprising administering into a tissue or cavity of said vertebrate in need of the therapy provided by said polypeptide the composition of claim 90;

wherein said polypeptide is a therapeutic polypeptide, and

wherein said therapeutic polypeptide is expressed in the vertebrate in a therapeutically effective amount.

100. A method of enhancing or modulating a vertebrate immune response comprising administering into a tissue or cavity of a vertebrate in need of such an enhanced or modulated immune response the composition of claim 90;

wherein said polypeptide is an immunogenic or immunomodulatory polypeptide, and wherein said immunogenic or immunomodulatory

polypeptide is expressed in the vertebrate in a sufficient amount to induce a desired immune response.

101. The method of claim 98, wherein said tissue is muscle.

102. The method of claim 101, wherein said tissue is skeletal muscle, smooth muscle, or myocardium.

103. A pharmaceutical kit comprising:

(a) a container holding about 1 ng to about 30 mg of a polynucleotide which operably encodes a polypeptide within vertebrate cells *in vivo*; and

(b) an amount of sodium phosphate which, when dissolved in an prescribed volume of distilled water, results in an aqueous solution with a molar concentration of said salt from about 20 mM to about 300 mM, or reaction, association, or dissociation products thereof;

whereby said polynucleotide is provided in a prophylactically or therapeutically effective amount to treat a vertebrate.